Innovative Research
for Orthopaedic Solutions

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SECTION 8: 510(k) SUMMARY

Prepared by J.R.J. Rowland,
Revised 2 July 2001

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92. It summarizes information presented in greater detail in the previous sections of this notification.

A. SUBMITTER

Xiros plc (incorporating Neoligaments)
28-30 Blenheim Terrace
Leeds
LS2 9HD
England

B. COMPANY CONTACT

Jim Rowland
Quality Assurance Manager

C. DEVICE NAME

1. Fastlok

Common name:	Fastlok Fixation Device
Classification name:	Staple, implantable
Class:	II
Classification:	21 CFR 888.3040

2. Poly-Tape

Common name:	Polyester Surgical Tape
Classification name:	Non-absorbable poly(ethylene terephthalate) surgical suture
Class:	II
Classification:	878.5000

D. PREDICATE LEGALLY MARKETED DEVICES

Acufex EndoButton with EndoButton Tape ("Endo-Tape") (Smith and Nephew Endoscopy, Mansfield MA).

E. DEVICE DESCRIPTION

The device is available as various combinations of Fastlok Fixation Devices with one or more Poly-Tapes, sold either in the same pack or separately.

The Fastlok Fixation Device comprises an orthopaedic fixation staple and a rectangular ring or "buckle plate". It is designed so that the Poly-Tape(s) follow a convoluted path through the staple and buckle, and this gives a slippage resistant grip on the Poly-Tape(s) when the staple is fully impacted. Fastloks are available in a range of sizes and made from various implantable metals, including Titanium Alloy ASTM F136 and Chrome-Cobalt-Molybdenum Alloy ASTM F75.

Poly-Tapes are woven implantable flat tapes, either single layer or tubular (double construction). They are available in extra-strong, dense or open woven construction, and in widths from $^1/_8$" - 1¼" (3mm to 30 mm) and length in the range of 12" – 32" (30 cm – 80 cm). They may be provided either with or without an attached standard stainless steel surgical needle at one end.

F. INTENDED USE

Poly-Tapes are single use devices intended to be used for soft tissue (tendon and ligaments) fixation to bone with a Fastlok Fixation Device during orthopaedic reconstruction procedures.

G. PERFORMANCE

The Fastlok/Poly-Tapes combination has been subject to thorough testing to provide data for comparison with that from similar tests of the predicate device combination. They are superior in stiffness and generally in strength (depending on size). The larger widths

available in the case of Poly-Tapes offer further advantages in terms of load spreading and reinforcement of the tissue to be joined.

H. TECHNOLOGICAL CHARACTERISTICS

The Fastlok Fixation Device is a two-component orthopaedic staple and buckle device designed for anchoring sutures and implantable tapes etc. to bone while allowing minimum slippage.

Poly-Tapes are flat suture tapes woven with various structures from poly(ethylene terephthalate). Table 8-1 *Equivalence comparison of Fastlok/Poly-Tapes with Endo-Button/EndoButton Tape* shows key technological characteristics including Design (construction), Materials, Performance, Sterility and Sizes (width and length).

I. SUBSTANTIAL EQUIVALENCE

The Fastlok/Poly-Tapes combination and the predicate device have superficially similar design, but differ in width of the tape element and exact method of manufacture (weaving v. braiding).

A point-by-point comparison of the Fastlok/Poly-Tape with their predicate device combination is given in Table 8-1 of this 510(k) Summary section. Further information on mechanical performance testing supporting the claim of equivalence is summarized in paragraph I, below.

The choice and control of materials and processes, and quality management systems complying with ISO 9001/EN 46001 and 21 CFR 820, all provide the necessary assurance of device safety, including sterility. The polyester used has a long history of safe implantation in a number of devices, and has been tested in accordance with selected tests from ISO 10993-1. The sterilization controls applied by Xiros plc to these devices are the same as those described in previous 510(k)s approved by FDA for Xiros sterile devices.

J. NON-CLINICAL PERFORMANCE TEST DATA

Xiros plc has conducted tensile tests of the 6 mm Fastlok used with 1 or 2 Poly-Tape loops in comparison with the predicate EndoButton/EndoButton Tape device combination. The two Poly-Tapes selected for test with the 6 mm Fastlok represent the least strong combinations among those included in this Notification. These were (a) the 3 mm Flat, Extra-strong Poly-Tape (102-1027/8) and (b) the 10 mm Flat Open Weave Poly-Tape (102-1010).

These tests showed that the 6 mm Fastlok combined with the 3 mm Flat, Extra-Strong Poly-Tape combination is slightly more strong and twice as stiff as the predicate combination. The 10 mm Flat Open Weave Poly-Tape was less strong than the predicate combination (though more stiff), unless two loops (4 ends) were used, and the requirement to use two loops of this Poly-Tape is listed under Warnings in the Package Insert Labelling.

Table 8-1 summarizes results obtained from testing representative Poly-Tapes with the 6 mm Fastlok.

Signed _____

J.R.J. Rowland
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2001

Mr. James R.J. Rowland
Quality Assurance Manager
Xiros PLC
28-30 Blenheim Terrace
Leeds LS2 9HD
England

Re: K010051
Trade/Device Name: Poly-Tapes for use with Fastlok Fixation Device
Regulation Number: 888.3040
Regulatory Class: II
Product Code: JDR
Dated: May 18, 2001
Received: May 24, 2001

Dear Mr. Rowland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

- Poly-Tapes are single use devices intended to be used for soft tissue (tendon and ligaments) fixation to bone with a Fastlok Fixation Device during orthopaedic reconstruction procedures.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010051